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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
SUVN-RK-006		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IN 03/00370	25.11.2003	28.11.2002
International Patent Classification (IPC) or both national classification and IPC		
C07D209/36		
Applicant		
SUVEN LIFE SCIENCES LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 24 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23.06.2004	24.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Zellner, A Telephone No. +49 89 2399-8078

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IN 03/00370

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-5, 8-22, 25, 26, 29-35, 43-76	as originally filed
6, 7, 23, 24, 27, 28, 36-42	received on 21.12.2004 with letter of 16.12.2004

Claims, Numbers

2 (part), 5 (part), 6	as originally filed
1, 2 (part), 3, 4, 5 (part), 7-17	received on 21.12.2004 with letter of 16.12.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

   see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 7-10,11,13-17

   because:

   ☒ the said international application, or the said claims Nos. 11,13-17 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 7-10

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-6,11-17
	No: Claims	
Inventive step (IS)	Yes: Claims	1-6,11-17
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-10,12
	No: Claims	

2. Citations and explanations

see separate sheet

1. The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

   D1: DATABASE CA [Online] CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; ICHIKAWA, HIDEJI ET AL: "3-(Amino acid-substituted)indoles for esterase and protease analysis" XP002276208 retrieved from STN Database accession no. 111:233670

   D2: WO 2004/000849 A (BATTULA SRINIVASA REDDY ;JASTI VENKATESWARLU (IN); KAMBHAMPATI RAM) 31 December 2003

   D3: DATABASE CROSSFIRE BEILSTEIN [Online] Beilstein Institut zur Förderung der Chemischen Wissenschaften, Frankfurt am Main, DE; XP002276209 Database accession no. 192292 (BRN)

   D4: DE 20 24 966 A (NOVO TERAPEUTSIK LABOR AS) 3 December 1970

   D5: DATABASE CROSSFIRE BEILSTEIN [Online] Beilstein Institut zur Förderung der Chemischen Wissenschaften, Frankfurt am Main, DE; XP002276213 Database accession no. 6876050 (BRN)

   D6: ANDERSEN, K.; ET AL.: J. MED. CHEM., vol. 39, 1996, pages 3723-3738, XP002276207

2. Amendments (Art. 34(2)(b), Rule 70.2(c) PCT)

2.1. Substituent R_{10} has been amended in claim 1. The new definition now covers "$_1$(C - C_3)alkyl". Originally disclosed, however, is only "(C_1-C_{12})alkyl". The amendment is thus not considered clearly and unambiguously disclosed in the application documents as originally filed. The amendment is not allowable with respect to Art. 34(2)(b) PCT.

2.2. The same applies to amended claims 7-10 and to the corresponding parts of the amended description.

2.3. This report is thus established as if the said amendment had not been made.

item III

3. For the assessment of the present claims 11 and 13-17 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

4. The international search report has not been established for claims 7-12 as originally filed due to a lack of unity of invention. These claims correspond to amended claims 7-10. The present report does thus not cover the examination of subject-matter according to claims 7-10 (Rule 66.1(e) PCT).

5. The present report furthermore does not extend to all of the presently claimed subject-matter because the international search report has not been established for all of the claimed subject-matter of originally filed claims 1-19 due to the fact that the definition of the subject-matter of these claims was considered unclear within the meaning of Art. 6 PCT. The amended set of claims would not appear to have been restricted in order to cover only searched subject-matter. The present report thus only relates to subject-matter for which a search has been carried out, i.e. to compounds as indicated by the specific formulae of the claims (Rule 66.1(e) PCT).

item **V**

6. Novelty (Art. 33(2) PCT)

6.1. The compounds of independent claim 1 are considered novel *vis-à-vis* D1 since the linker $C(R_{11})(R_{12})$ cannot be carbonyl as it is in D1. None of the remaining documents discloses compounds falling within the scope of present claim 1. As a consequence, the subject-matter of claims 2-6 and 11-17 is considered novel as well.

6.2. No opinion is given for claims 7-10 (see under point 4 of this report).

7. Inventive step (Art. 33(3) PCT)

Document D6 relates to structurally related compounds and their use as serotonin 5-HT receptor antagonists. D6 is considered as to represent the most relevant state of the art. The compounds of amended claim 1 differ from compounds disclosed in D6 in the nature of the substituent at the N-atom of the indole basic structure. According to the description of the present application, the claimed compounds are useful for treating several diseases associated with the modulation of Melatonin or serotonin 5-HT receptor (p. 1, l. 20ff). Since neither D6 nor any of the other cited documents appear to provide an indication for the substitution of a group as disclosed in D1 by a phenyl sulphonyl group according to claim 1, presence of an inventive step could be acknowledged for claims 1-6 and 11-17, as far as they have been searched (see above). The requirements of Art. 33(3) PCT are thus met.

8. Industrial applicability (Art. 33(4) PCT)

Can be acknowledged for claims 1-10 and 12.

9. Document D2, which was published after the filing date of the present application but claims a priority date which is before the priority date of the present application will be considered for the question of novelty in the regional european phase.

10. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents cited in the ISR is not mentioned in the description, nor are these documents identified therein.

11. The expressions "pharmaceutically acceptable salts", "pharaceutically acceptable solvates", "useful bio-activ metabolites", "derivatices", "prodrug" and "protective groups" do not have a precise meaning in the art of chemistry. They are thus not considered suitable for the definition of any subject-matter. Claims containing the said expressions are thus not considered as to meet the requirements of Art. 6 PCT.